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Block Drug Company, Inc.
Amendment to Application for Exemption for BC® analgesic powder (two doses)

Block Drug Company, Inc. (Block) is amending Option 2 of its Application for Exemption for BC® analgesic powder (two doses). Block incorporates by reference its January 28, 2000, submission, as amended August 22, 2000, as well as the December 22, 2000, letter from Robert A. Dormer to Dr. Charles A. Ganley.

21 C.F.R. § 201.66(c) Content Requirements

In addition to the previously requested exemption from the requirement in 21 C.F.R. § 201.66(c) that the outside container or wrapper of the retail package contain all of the information specified in paragraphs (c)(1) through (c)(8), Block herein requests exemption from the requirement in 21 C.F.R. § 201.66(c) that the information be placed in the order listed. First, Block requests that it be permitted to place the “inactive ingredients,” 21 C.F.R. § 201.66(c)(8), immediately after the “active ingredients,” 21 C.F.R. § 201.66(c)(2), on its product label so that the inactive ingredients will be on the outside package at the time of purchase of the product. Second, Block requests that it be permitted to place the “Keep out of reach of children” warning required by 21 C.F.R. § 201.314(a) for products containing salicylates immediately after the Reye’s syndrome warning so that this warning will be visible on the outside package at the time of purchase of the product. See Appendix 10.

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Appendix 6 (Option 1 Proposed Labeling – Type Size Reduced and Format Revised to Accommodate Information on Package of Same Size as Current Package)

Appendix 7 (Option 1 Annotated Labeling)

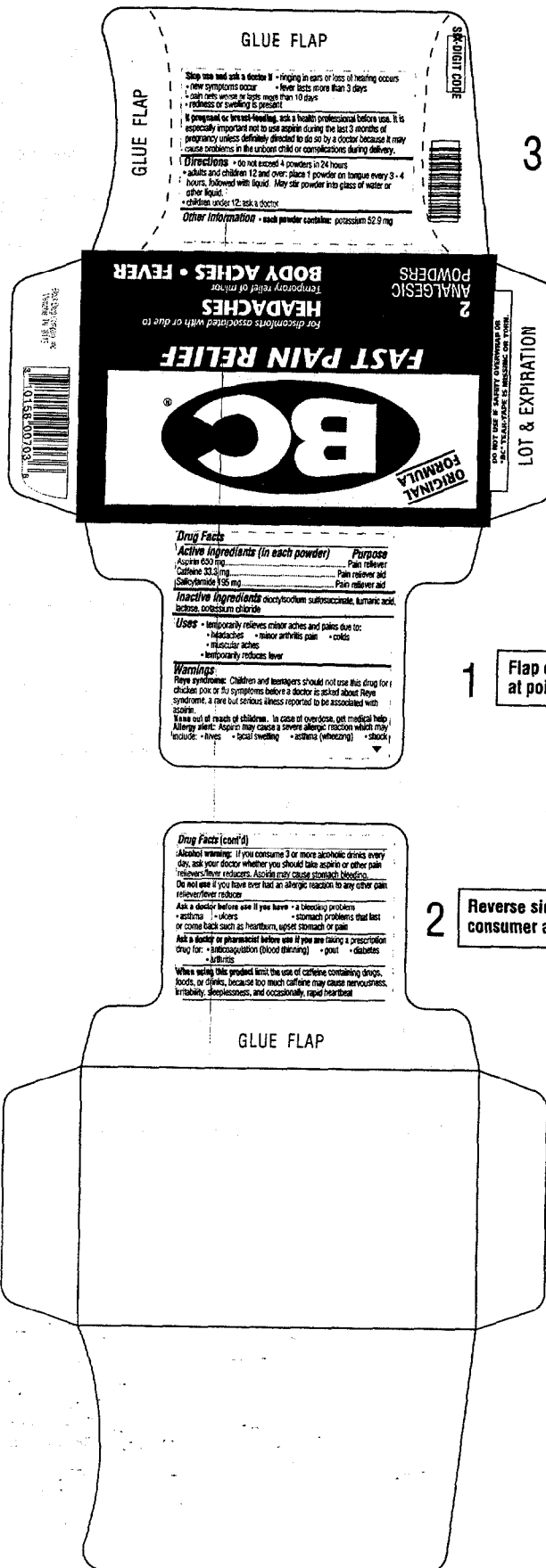
Appendix 8 (Option 2 Proposed Labeling – Package Flap Includes Required Information on Interior and Exterior of Flap)

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Appendix 10 (Amended Option 2 Annotated Labeling)

Appendix 10

Amended Option 2 – Annotated Labeling



3

Panel concealed by flap;
copy not visible to consumer
at point of purchase

1

Flap copy visible to consumer
at point of purchase

2

Reverse side of flap; not visible to
consumer at point of purchase

Title: 8.1 pt.
Headings: 8 pt.
Sub-Headings: 6 pt.
Body: 6 pt.
Leading: 6.5 pt.
Font: Helvetica Condensed
Bullet: 5 pt.
em's between bullets: 2

Project Number: BC-015
File Name: BC 2's-standard
Revision: 4
Date: 01-04-2000
Designer: tam



**CREATIVE SERVICES
GRAPHICS**

NOTE: • GREY DASHED LINE WILL NOT PRINT
• BLUE DASHED LINES REPRESENT
THE ENVELOPE OVERLAP
• ALL TOLERANCES MEET REQUIREMENTS